

REMARKS

The Office Action raised an issued in the specification as to the phrase “blood amount” and “a blood component amount” in certain paragraphs and the claims which has now been addressed.

It is believed that the submission of the new claims 31 to 40 more than adequately addresses both the 35 U.S.C. §112 and 35 U.S.C. §101 issues.

The Office Action also raised an issue of a provisional double patenting rejection based on a co-pending and subsequently filed 2004 U.S. Patent Application 2004/0236197. This application is now issuing as U.S. Patent No. 7,142,902 and already has a Terminal Disclaimer disclaiming the term of that patent over the present application.

Since this is a provisional obviousness-type double patenting rejection and a Terminal Disclaimer was filed based on the present application in the later filed application, it is believed that this issue of obviousness double patenting is now moot.

The Office Action rejected each of the outstanding original claims as being completely anticipated by *Hoshi et al.* “Near-Infrared Optical Detection of Sequential Brain Activation in the Pre-Frontal Cortex During Mental Task.” This 1996 publication observed that the changes in total hemoglobin in one brain region varied with time and “might reflect mental processes.” The article took eight healthy volunteer subjects and calculated arbitrary baseline values of oxy-Hb and deoxy-Hb for the changes for absorption by certain wavelengths in the near infrared region. The subjects were provided with three different mathematical problems and relative changes in the respective right and left pre-frontal cortices were measured during the solving of each of the problems.

As noted on Page 293, the dynamic features of the changes in the regional brain activity during the solving of the problem were found to be different from subject to subject in the same brain region, and also different from each other between the right and left pre-frontal cortices.

The conclusion was:

“At the moment, we have no explanation for the reason why mental tasks have residual effects on the oxygenation and hemodynamics in the pre-frontal cortex.”

In essence, the study simply suggests a region, dependent temporal variations of brain activity appeared to be observed and may reflect mental processes.

Our present invention makes it possible to objectively, in a specific manner, determine a point in time when the average value of a blood amount component such as deoxy-Hb or oxy-Hb changes from an increasing to a constant state or a decreasing state. This change has been determined by our inventors to correspond to the time at which a person acquires or learns a skill when a person is performing a work assignment.

Thus, the present invention is capable of measuring a degree of acquisition of a work skill in accordance with an objective scientific data concerning work performed by a subject from a time change data and a deoxy-Hb amount in blood by a predetermined measurement in a region of the brain of the subject, while the subject repeatedly performs the work.

An acquisition degree determining portion is configured to determine that the acquisition degree is low when the deoxy-Hb amount increases on the initiation of the work, and to determine the acquisition degree is high when the deoxy-Hb amount remains generally unchanged or decreases, irrespective of time change, and diachronic change data during the work. Thus, the present inventors provide an ability to objectively know the acquisition degree of the subject to a particular type of work.

The Office Action relied upon a selective assumption from the observations disclosed in the *Hoshi et al.* reference. Basically, the *Hoshi et al.* reference can be relied upon to verify that the two regions of the pre-frontal cortex when measured simultaneously disclosed changes in oxygenation and hemodynamics that might have a potential for imaging a sequence of brain activation.

As noted in *In re Felton* (CCPA 1973) 179 U.S.P.2Q. 298:

"In this regard we do not disagree with the board's apparent conclusion that an intermediate structure made for the Sand's device could possess the characteristics called for in these claims. However, in view of the purpose for which the Sand's device is intended, it is apparent that it requires no critical dimension which would lead to a structure inherently having those characteristics. Therefore, it would be mere happenstance if any structure made according to Sands met the limitations of the claims. An accidental or unwitting duplication of an invention cannot constitute an anticipation. *Tilghman v. Proctor*, 102 U.S. 707 (1880); *Eibel Process Co. v. Minnesota and Ontario Paper Co.*, 261 U.S. 45 (1923). For this reason, we do not believe that Sands has 'identically disclosed or described' the invention as required of an anticipatory reference applied under section 102. The disclosure as a whole cannot be considered to sufficiently direct one skilled in the art to the invention which is a single drop dispenser requiring the critical dimensions."

Our invention provides a device to measure the degree of acquisition of a work skill task in an objective scientific manner from time change data in deoxy-Hb amount in blood and a predetermined measuring region of the brain of the subject when the subject repeatedly performs the work several times. The *Hoshi et al.* reference does not teach, disclose or suggest making a determination of when it's subject actually acquired a learning skill and it certainly does not suggest that it was known in the art that the evaluation as done by our present invention could be a result effective variable in making such determinations.

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might

be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.).

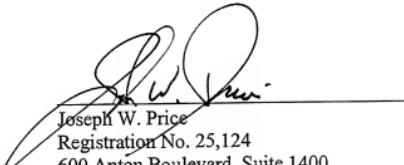
(Underline Added)

MPEP § 2144.05 (II) (B)

In view of the submission of newly drafted claims and the above comments, it is believed that the present case is in condition for allowance and early notification of the same is requested. If the Examiner believes a telephone interview would assist in the prosecution in this case, he is respectfully requested to contact the undersigned attorney at the listed telephone number.

Very truly yours,

**SNELL & WILMER L.L.P.**



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